DM-10/2003

AF 1641
IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Re: Appeal to the Board of Patent Appeals and Interferences

In re Application of:	Rouns, et al.	Group Art Unit:	1641
Serial No.:	09/733,161	Examiner:	Ann Lam
Filed:	December 8, 2000	Our Customer ID:	22827
For:	Silicone Elastomer Material For Use With Enteric Feeding Device	Our Account No:	04-1403
Sir:		Attorney Ref:	BAL-36 (BA-00170)

1. [ ] **NOTICE OF APPEAL**: Pursuant to 37 CFR 1.191, Applicant hereby appeals to the Board of Appeals from the decision dated ____ of the Examiner twice/finally rejecting claims ____.
2. [X] **BRIEF** on appeal in this application pursuant to 37 CFR 1.192 is transmitted herewith in triplicate.
3. [ ] An **ORAL HEARING** is respectfully requested under 37 CFR 1.194 (due within one month after Examiner's Answer).
4. [ ] Reply Brief under 37 CFR 1.193(b) is transmitted herewith in triplicate.
5. [ ] "Small entity" verified statement filed: [ ] herewith [ ] previously.
6. **FEE CALCULATION:**

	Fees
If box 1 above is X'd enter $330.00	$_____
If box 2 above is X'd enter $330.00	$330.00
If box 3 above is X'd enter $290.00	$_____
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Petition is hereby made to extend the original due date of June 9, 2004, to cover the date of this paper and any enclosure for which the requisite fee is (1 month $110); (2 months $420); (3 months $950); (4 months $1,480).	$_____
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If "small entity" box 5 above is X'd, enter one-half (1/2 of subtotal and subtract)	- $_____
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[ ] Charge fee to our Deposit Account/Order Nos. in the heading hereof (for which purpose one additional copy of this sheet is attached)
[ ] Fee NOT required since paid in prior appeal in which the Board of Appeals did not render a decision on the merits.

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DORITY & MANNING, ATTORNEYS AT LAW, P.A.

By: Tara E. Agnew Reg. No: 50,589
Signature: Tara E. Agnew
Date: June 8, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, Post Office Box 1450, Alexandria, VA 22313-1450, on June 8, 2004.

Sandra S. Perkins
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Sandra S. Perkins
(Signature of person mailing paper or fee)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS AND INTERFERENCES

Applicants:	Rouns, et al.	Examiner:	Ann Lam
Appl. No:	09/733,161	Art Unit/T.C.:	1641
Filed:	December 8, 2000	Customer No:	04-1403
Title:	Silicone Elastomer Material for Use with Enteric Feeding Device	Customer ID No:	22827
		Confirmation No:	2368

BRIEF ON APPEAL

Mail Stop Appeal Briefs – Patents
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the communications dated October 7, 2003 and April 7, 2004 for the above-captioned patent application, Appellant submits the following Brief On Appeal in accordance with 37 C.F.R. § 1.192.

1. Real Party in Interest

The real party in interest with respect to the above-captioned application and with respect to this appeal is Kimberly-Clark Worldwide, Inc.

2. Related Appeals and Interferences

Appellant is not aware of any other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of the Claims

Claims 1-8 and 10-26, all of which are attached hereto as Appendix A, are currently pending in the present application, including independent claims 1, 13, and

20. Previously, claim 9 was cancelled. Claims 1-8 and 10-26 (all the pending claims) are being appealed.

In a Final Office Action mailed October 7, 2003, claims 1-8 and 10-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,834,721 to Onohara, et al. in view of U.S. Patent No. 4,198,983 to Becker, et al. Additionally, independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,439,443 to Miyata, et al. in view of U.S. Patent No. 4,604,412 to Joh, et al.

4. Status of Amendments

Appellant filed a Response After Final on February 9, 2004, including only Remarks/Arguments with no claim amendments. In an Advisory Action mailed April 7, 2004, the Examiner indicated that the request for reconsideration had been considered but did not place the application in condition for allowance, stating that for purposes of Appeal, the "proposed amendment(s)" would not be entered. Accordingly, claims 1-8 and 10-26 (attached hereto as Appendix A and last amended on July 10, 2003) are the subject of this appeal.

5. Summary of the Invention

The present invention is generally directed to a gastrostomy feeding device that has improved resistance to acidic and enzymatic degradation when placed in the stomach of a patient. (Appl. p. 2, lines 14-17). The gastrostomy device of the present invention may be inserted into the gastro-intestinal tract of a patient in order to insert substances into or remove substances from the body. (Appl. p. 6, lines 3-9).

Specifically, the gastrostomy device includes an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet. (Appl. p. 2, lines 17-19). The device further includes an anchoring means mounted on the feeding tube to retain the feeding tube within the stomach, and this anchoring means includes at least one internal retaining member comprised of a modified silicone elastomer.[1] (Appl. p. 2, lines 19-23).

The modified silicone elastomer that makes up the internal retaining member may be a fluoro-modified silicone (such as a fluoro-modified polysiloxane), a phenyl-modified silicone (such as a phenyl-modified polysiloxane), or combinations thereof. (Appl. p. 3, line 1 – p. 4, line 3). It has been discovered that internal retaining members made from such modified silicones have increased resistance to acidic and enzymatic degradation when placed into the stomach of a patient. (Appl. p. 5, lines 5-13). Similarly, it has been discovered that such modified silicones improve the burst strength of the internal retaining members. (Appl. p. 8, lines 7-12).

For instance, Examples 1-4 illustrate that feeding devices made according to Appellant's present invention exhibit improved resistance to acidic and enzymatic degradation as well as improved burst strength when compared to conventional feeding devices made, for example, from conventional organopolysiloxane. (Appl. pp. 11-15). Thus, the inclusion of phenyl-modified silicone, fluoro-modified silicone, or combinations thereof in an internal retaining member of Appellant's claimed gastrostomy feeding

[1] At page 7 of the Final Office Action, the Examiner stated that applicants have "not clearly defined what comprises the internal retaining member." Appellant respectfully submits that the claims, the specification, and the drawings make clear that the gastrostomy feeding device of the present invention includes an elongated feeding tube on which is mounted an anchoring means having at least one internal retaining member. Thus, the internal retaining member is clearly a separate element from the elongated feeding tube.

device results in a feeding device having an extended useful life because of the device's increased acid resistance, increased resistance to enzyme degradation, and increased strength. (See Appl. p. 15, lines 3-14).

6. Summary of the Issues

I. Are claims 1-8 and 10-26 patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,834,721 to Onohara, et al. in view of U.S. Patent No. 4,198,983 to Becker, et al.?

II. Is claim 1 patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,439,443 to Miyata, et al. in view of U.S. Patent No. 4,604,412 to Joh, et al.?

7. Grouping of the Claims

For each ground of rejection which Appellant contests, Appellant has grouped the pending claims as follows:

With regard to the rejection of claims 1-8 and 10-26 under 35 U.S.C. § 103 using Onohara, et al. and Becker, et al.:

Group	Claims Included
1	1-8 and 10-26 (all pending claims)

With regard to the rejection of claim 1 under 35 U.S.C. § 103 using Miyata, et al. and Joh, et al.:

Group	Claims Included
2	1

8. Argument

I. Claims 1-8 and 10-26 Are Not Obvious Under 35 U.S.C. § 103(a) Over U.S. Patent No. 4,834,721 to Onohara, et al. in view of U.S. Patent No. 4,198,983 to Becker, et al.

Onohara, et al. is directed to a composite shaped article made from a thermoplastic resin and silicone rubber. (Col. 3, lines 6-16). In certain embodiments, Onohara, et al. describes a catheter tube with a balloon. (Col. 3, lines 61-67). However, as opposed to the currently pending claims and as conceded in the Final Office Action, Onohara, et al. fails to disclose an anchoring means for a gastrostomy feeding device that includes an internal retaining member comprised of a modified silicone elastomer selected from the group consisting of a phenyl-modified silicone and/or a fluoro-modified silicone.

Nevertheless, Becker, et al. was combined with Onohara, et al. in an attempt to render claims 1-8 and 10-26 obvious. Becker, et al. discloses a balloon-type catheter comprising an inflatable balloon member and a tubular shaft. (Col. 2, lines 12-16). The ***tubular shaft*** of Becker, et al.'s catheter consists essentially of from 40 to 70% by weight of an elastic composition which comprises from 50 to 99.5% by weight of a block copolymer having thermoplastic rubber characteristics with a central, rubbery polyolefin block and terminal blocks of a polystyrene. The block copolymer preferably exhibits a Brookfield viscosity at 25°C at 10 to 2000 cps., when measured using a 10% by weight solids solution in toluene. The composition also may contain up to 45% by weight of polypropylene, and from 0.5 to 10% by weight of a cross-linked silicone elastomer, preferably no more than 5 percent. Added to this is preferably 30 to 60% by weight of a

hydrophobic oil-type plasticizer to provide a desired degree of softness to the elastic composition. (Col. 2, lines 16-35). Becker, et al. states that addition of the silicone provides the catheter shaft with increased slippery characteristics. (Col. 5, lines 54-57).

As opposed to the currently pending claims, however, Becker, et al. only teaches using a cross-lined silicone elastomer to form the catheter ***shaft*** and teaches using other materials to form a balloon retaining member. Nonetheless, in the Final Office Action, the Examiner asserted that Onohara, et al. discloses that a catheter tube and balloon may each be made of the same material due to the following passage in Onohara, et al.:

> [T]here can be provided a catheter tube with a balloon wherein the catheter tube and the balloon are each made of a same or different thermoplastic resin or silicon rubber and, at the balloon-fixing portion of the catheter tube, the catheter tube and the balloon are bonded strongly with an addition polymerization type silicone composition of the present invention. This catheter tube with a balloon enables wide and flexible selection for material combination of tube main body and balloon.

(Col. 9, lines 12-21). Based on the above-quoted passage, it was asserted that the siloxane disclosed in Becker, et al. may be used to form a catheter tube and balloon since Onohara, et al. teaches that a catheter shaft and balloon may be each made of the same material.

A. No Suggestion or Motivation Exists to Combine Onohara, et al. with Becker, et al. in the Manner Proposed in the Office Action.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion, motivation, or incentive (either in the references themselves or in the knowledge generally available to one of ordinary skill in the art) to

modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. See In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).

An applicant's claimed invention taken as a whole cannot be said to be obvious without some reason given in the prior art why one of ordinary skill would have been prompted to modify the teachings of the references to arrive at the claimed invention. See In re Regel, 188 U.S.P.Q. 132 (C.C.P.A. 1975). The mere fact that the prior art *may* be combined or modified in the manner proposed by the Examiner does not make the combination or modification obvious unless the prior art suggested the desirability of the combination or modification. In re Fritch, 12 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992); In re Mills, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Thus, where no reasonable intrinsic or extrinsic justification exists in the prior art for the proposed combination or modification, a case of *prima facie* obviousness will not have been established.

In this case, Appellant respectfully submits that no motivation or suggestion existed at the time of the present invention for one of ordinary skill in the art to combine Onohara, et al. and Becker, et al. in the manner proposed in the Final Office Action. To arrive at Appellant's claimed gastrostomy feeding device, there must be some motivation, suggestion or incentive in these references to form an internal retaining

member from a modified silicone elastomer selected from a phenyl-modified silicone and/or a fluoro-modified silicone. Appellant asserts that neither Onohara, et al. nor Becker, et al. provides the necessary motivation, suggestion or incentive to render Appellant's pending claims obvious.

For instance, the entire focus of Onohara, et al. is producing a composite shaped article from (a) thermoplastic resins (soft vinyl chloride resins, olefin resins, urethane resins and styrene resins) and (b) silicone rubbers, wherein "the strong points of the materials (a) and (b) are utilized." (Col. 3, lines 6-16). And Onohara, et al. merely states that a catheter tube and a balloon may be made from a same or different thermoplastic resin or silicone rubber. Nowhere does Onohara, et al. even disclose a phenyl-modified silicone or a fluoro-modified silicone, let alone any type of teaching to use one of these materials in forming a balloon or an internal retaining member on a catheter.

Becker, et al., on the other hand, states that the ***shaft*** of a catheter can be made from a thermoplastic material containing, as one ingredient, a cross-linked organic silicone elastomer in order to increase the slipperiness of the shaft. With respect to the balloon retaining member, however, Becker, et al. specifically teaches forming the balloon material from a mixture of block copolymers (such as block copolymers of poly(ethylene-butylene) having terminal blocks of polystyrene), mineral oil, titanium oxide pigment, and an amide of erucic acid. (Col. 5, line 58 – col. 6, line 12). Thus, Becker, et al. fails to provide any motivation, suggestion or incentive to construct a balloon or an internal retaining member from a phenyl-modified silicone and/or a fluoro-

modified silicone.[2]

As such, it is believed that the claims patentably define over Onohara, et al. either alone or in combination with Becker, et al. because without a motivation to combine these references, a prima facie case of obviousness has not been made. See In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998).

Appellant emphasizes that the teachings of the references must be viewed *in their entirety* to sustain a *prima facie* case of obviousness under 35 U.S.C. § 103. Further, the appropriate test under 35 U.S.C. § 103 is not whether the differences between the prior art and the claims are obvious, but instead whether the *claimed invention as a whole* would have been obvious. In this case, Appellant respectfully submits that when the Onohara, et al. and Becker, et al. reference teachings are properly viewed in their entirety, there is simply no motivation or suggestion—explicit or implicit—to combine the references in the manner proposed by the Office Action and arrive at Appellant's claimed gastrostomy feeding device.

B. The References Teach Away From the Modification/Combination Made by the Examiner.

Not only was there no motivation at the time of the present invention to combine

[2] Again, at page 7, the Office Action asserted that applicants have not clearly defined what comprises the internal retaining member of the claimed feeding device. The pending claims specifically recite an elongated feeding tube and an internal retaining member, where the internal retaining member is clearly a separate element from the elongated feeding tube. In this same portion of the Office Action, the Examiner made the overbroad statement that "since Onohara, et al. teaches that a catheter may be made of a silicone rubber, and Becker, et al. teaches that a catheter can be made of diphenylsiloxane, it would have been obvious to provide diphenylsiloxane as the silicone rubber used to form the Onohara, et al. catheter." The Examiner misstates the teachings of Becker, et al.; Becker, et al. teaches making only the ***shaft*** of a catheter out of a very specific elastic composition that may contain certain cross-linked organic silicone elastomers. Becker, et al. does not generally teach making a catheter out of diphenylsiloxane nor does Becker, et al. teach making the balloon portion (the internal retaining member portion) of its catheter out of such silicone elastomers.

Onohara, et al. with Becker, et al. in the manner proposed by the Office Action, the references themselves teach away from the Examiner's proposed combination or modification. Again, in the Final Office Action, the Examiner generally stated that the siloxane materials disclosed in Becker, et al. may be used to form not only a catheter tube but also a balloon or internal retaining member since Onohara, et al. teaches that a catheter shaft and balloon each may be made of the same material. Appellant respectfully disagrees.

Appellant submits that Becker, et al. teaches away from forming an internal retaining member or balloon of a gastrostomy feeding device from a phenyl-modified silicone and/or a fluoro-modified silicone. Specifically, Becker, et al. clearly delineated *different* materials that make up the shaft of its catheter and the balloon portion of its catheter. In particular, Becker, et al. *only* describes that the balloon portion (the internal retaining member) of its catheter is made of a mixture of block copolymers (such as block copolymers of poly(ethylene-butylene) having terminal blocks of polystyrene), mineral oil, titanium oxide pigment, and an amide of erucic acid (col. 5, line 58 – col. 6, line 12), while Becker, et al. describes that the shaft or tube portion of its catheter is made of a specific elastic composition of block copolymers that may include a cross-linked organic silicone elastomer. (Col. 2, lines 16-33). Thus, Becker, et al. teaches away from a catheter wherein the balloon portion (internal retaining member) and the tube or shaft portion are made from the same materials. Accordingly, Appellant respectfully submits that this "teaching away" demonstrates a lack of *prima facie* obviousness of the subject claims. See In re Fine, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

C. The Onohara, et al. and Becker, et al. References, When Combined, Do Not Teach or Suggest All the Claim Limitations.

Moreover, *any* combination of the Onohara, et al. and Becker, et al. references would still fail to teach or suggest some of Appellant's claim limitations. For instance, all 3 independent claims of the present application require a gastrostomy feeding device that includes a feeding inlet contained on an elongated feeding tube. Neither Onohara, et al. nor Becker, et al. discloses or suggests a gastrostomy feeding device that includes a feeding inlet contained on an elongated feeding tube. Thus, Appellant respectfully submits that because all the limitations of the pending claims are not taught or suggested by Onohara, et al. or Becker, et al.—alone or in combination—a *prima facie* case of obviousness has not been established. See In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

D. The Office Action's Combination of Onohara, et al. and Becker, et al. Stems Improperly from the Teachings of the Present Invention.

In short, it appears that the Office Action's combination of Onohara, et al. with Becker, et al. stems from the teachings of Appellant's present invention, which is improper. The Federal Circuit has repeatedly warned against using the applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art. See Grain Processing Corp. v. American Maize-Products, 5 U.S.P.Q.2d 1788 (Fed. Cir. 1988). Thus, the mere fact that the prior art *may* be combined or modified in the manner proposed by the Examiner does not make the combination or modification obvious unless the prior art suggested the desirability of the combination or modification. In re Fritch, 12 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

In the Advisory Action, the Examiner again stated that Onohara, et al. teaches that the same material used for forming the catheter shaft can be used for forming the balloon, stating: "Thus, Onohara, et al. provides the motivation for using the materials disclosed by Becker, et al. for forming the catheter shaft to also form the balloon." Clearly, the Examiner's modification of Onohara, et al. using Becker, et al. results *improperly* from using Appellant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art. Again, no suggestion or motivation whatsoever—whether explicit or implicit—existed in the prior art for combining the teachings of Onohara, et al. and Becker, et al. Accordingly, it is respectfully submitted that any combination of Onohara, et al. and Becker, et al. impermissibly relies on the use of hindsight, and hindsight cannot be successfully used to support a *prima facie* case of obviousness. Thus, a *prima facie* case of obviousness has not been established.

II. Claim 1 Is Not Obvious Under 35 U.S.C. § 103(a) Over U.S. Patent No. 5,439,443 to Miyata, et al. in view of U.S. Patent No. 4,604,412 to Joh, et al.

Miyata, et al. is directed to a balloon catheter for use in intraaortic balloon pumping (IABP) in the treatment for heart failure caused by myocardial infraction. (Col. 1, lines 6-14). Miyata, et al. explains that in IABP, a balloon attached to the tip of a catheter is synchronized with electrocardiography, so as to deflate it at systole of a ventricle and inflate it at diastole of the ventricle. (Col. 1, lines 14-22). This inflation is conducted by a pumping system. (Col. 1, lines 23-31).

The balloon catheter of Miyata, et al. includes a balloon part composed of a film

which is formed from a polymer having a number average molecular weight of at least 50,000 and has an initial modulus at 100% of at least 95 kg/cm^2. (Col. 3, lines 7-15). Miyata, et al. specifically states that such a balloon part exhibits good wear resistance against the calcified deposit present in an aorta that typically causes destruction of the balloon part when, upon repeated inflation and deflation, the balloon rubs against this calcified deposit located on the inner wall of the blood vessel. (Col. 2, line 28 – col. 3, line 15). Miyata, et al. generally describes that various polymers including polyurethane, polyurethane urea, polyurethane-silicone block copolymers, fluorinated polyurethane, fluorinated polyurethane urea, and the like may be used in the balloon catheter and that such polymers may be blended, for instance, with polydimethylsiloxane. (Col. 3, lines 35-44).

Miyata, et al. does not disclose or suggest a gastrostomy feeding device having improved resistance to acidic and enzymatic degradation that comprises an elongated feeding tube that includes a feeding inlet, nor does Miyata, et al. disclose or suggest an anchoring means, mounted on a feeding tube, that includes an internal retaining member comprised of phenyl-modified silicone, fluoro-modified silicone, or combinations thereof. Nevertheless, Miyata, et al. was combined with Joh, et al. to reject independent claim 1 in the Final Office Action.

Joh, et al. is directed to a stable polymer emulsion composition capable of providing a thromboresistant surface, where the composition comprises polyurethane, a polydiorganosiloxane, and a cyclic ether. The polydiorganosiloxane is dispersed as particles having an average particle diameter of 0.1 to 50 microns in a solution of the

polyurethane in the cyclic ether, and at least a part of the surfaces of the particles are crosslinked. Joh, et al. mentions intravascular dwelling catheters as medical devices that come into contact with blood and that require antithrombogenic properties (anti-clotting, or anti-coagulating properties) in their therapeutic use. Further, Joh, et al. states that the polydiorganosiloxane used in the emulsion composition is preferably polydimethylsiloxane, but also may be, for example, polydiethylsiloxane, polymethylphenylsiloxane, dimethylsiloxane/diphenylsiloxane copolymer, or polymethylphenylvinylsiloxane.

The Office Action stated that "since Miyata, et al. teach that a medical balloon can be comprised of polydimethylsiloxane" and because Joh, et al. teaches that a "material comprised of diphenylsiloxane develops better antithrombogenic properties desirable for blood-contact medical devices, it would have been obvious that the Miyata, et al. polydimethylsiloxane can be substituted with diphenylsiloxane composition taught by Joh, et al. in order to develop better antithrombogenic properties." (Final Office Action, p. 6).

A. The Miyata, et al. and Joh, et al. References, When Combined, Do Not Teach or Suggest All the Claim Limitations.

Appellant respectfully submits that *any* combination of the Miyata, et al. and Joh, et al. references would still lack several of the limitations of Appellant's independent claim 1. Specifically, as opposed to claim 1, neither reference discloses or suggests a gastrostomy feeding device that includes an elongated feeding tube, having a first end for insertion through a patient's abdominal wall and a second end that includes a

feeding inlet, and an anchoring means mounted on the feeding tube to retain the tube within the patient's stomach.

For instance, at page 5 of the Office Action, the Examiner stated that Miyata, et al. discloses "a tube and an anchoring means mounted on the tube capable of retaining said feeding tube within the stomach," citing column 1, line 23 and column 2, lines 26-27 for this entire combination of structures. However, these cited portions of Miyata, et al. simply state the words "balloon catheter used in IABP" and "a balloon catheter having a balloon part." *Nowhere* in Miyata, et al. is there any description of or reference to a gastrostomy feeding device comprising an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet.

Similarly, nothing in Joh, et al. remedies these deficiencies in the teachings of Miyata, et al. In Joh, et al., the only devices described as being constructed from a film or coating that includes Joh, et al.'s stable polymer emulsion composition are devices having a blood-contact surface, for example an intravascular dwelling catheter, a cannula, an extra-corporeal blood circulating circuit, a blood bag, a ventricular assistant device, an artificial heart, and an intraaortic balloon pump. (Col. 6, lines 36-48). Joh, et al. does not include any description of or suggestion regarding a gastrostomy feeding device that comprises an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet, with an anchoring means mounted on the feeding tube to retain the feeding tube within the patient's stomach.

Simply put, all words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 165 U.S.P.Q. 494 (C.C.P.A. 1970). And in this case, not all of the limitations of claim 1 are taught or suggested by the combination of the Miyata, et al. and Joh, et al. references. Thus, a prima facie case of obviousness has not been established.

Appellant again emphasizes that the teachings of the references must be viewed *in their entirety* to sustain a *prima facie* case of obviousness under 35 U.S.C. § 103. In this case, Appellant respectfully submits that when the Miyata, et al. and Joh, et al. reference teachings are properly viewed in their entirety, independent claim 1 patentably defines over such references. Again, in both of these documents, the only discussion of balloon-type catheters (where the balloon portion might be considered an "internal retaining member") refers exclusively to intraaortic balloon pumping devices, and Miyata, et al. and Joh, et al. focus on phenomena that occur inside parts of a patient's *circulatory* system (i.e., the aorta, ventricles, heart, blood vessels, and the like). Nothing in Miyata, et al. and/or Joh, et al. teaches or suggests a gastrostomy feeding device according to Appellant's claim 1. Accordingly, Appellant respectfully submits that claim 1 is patentable over the combination of Miyata, et al. and Joh, et al.

9. Conclusion

Claims 1-8 and 10-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,834,721 to Onohara, et al. in view of U.S. Patent No. 4,198,983 to Becker, et al. Additionally, claim 1 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,439,443 to Miyata, et al. in view

of U.S. Patent No. 4,604,412 to Joh, et al.

However, at the time of the present invention, no motivation or suggestion existed for combining the Onohara, et al. and Becker, et al. references in the manner proposed by the Final Office Action. In fact, Becker, et al. actually teaches away from the combination or modification proposed by the Examiner. The Office Action's combination of the Onohara, et al. and Becker, et al. references appears to stem from the teachings of Appellant's disclosure, which is improper. Additionally, the Miyata, et al. and Joh, et al. references, when combined, do not teach or suggest all of the limitations of Appellant's claim 1.

As such, a *prima facie* showing of obviousness has not been made, and Appellant is entitled to the issuance of a patent.

Respectfully submitted,

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Date: June 8, 2004

APPENDIX A

In the Claims:

1. A gastrostomy feeding device having improved resistance to acidic and enzymatic degradation comprising an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet, and an anchoring means mounted on the feeding tube to retain said feeding tube within the stomach, wherein said anchoring means has at least one internal retaining member comprised of a modified silicone elastomer selected from the group consisting of phenyl-modified silicone, fluoro-modified silicone, and combinations thereof.

2. The gastrostomy feeding device according to claim 1, wherein the modified silicone elastomer is a member selected from the group consisting of trifluoropropylsiloxane modified dimethylpolysiloxane, diphenylsiloxane modified dimethylpolysiloxane, and combinations thereof.

3. The gastrostomy feeding device according to claim 2, wherein said modified silicone elastomer is a trifluoropropylsiloxane modified dimethylpolysiloxane.

4. The gastrostomy feeding device according to claim 2, wherein said modified silicone elastomer is a diphenylsiloxane modified dimethylpolysiloxane.

5. The gastrostomy feeding device according to claim 3, wherein the trifluoropropylsiloxane content of said elastomer is from about 5 to 95 mole percent.

6. The gastrostomy feeding device according to claim 5, wherein the trifluoropropylsiloxane content of said elastomer is from about 40 to 60 mole percent.

7. The gastrostomy feeding device according to claim 4, wherein the

diphenylsiloxane content of said elastomer is from about 0.5 to 50 mole percent.

8. The gastrostomy feeding device according to claim 7, wherein the diphenylsiloxane content of said elastomer is from about 10 to 25 mole percent.

10. The gastrostomy feeding device according to claim 4, wherein the diphenylsiloxane content of the elastomer is less than about 10 mole percent.

11. The gastrostomy feeding device according to claim 4, wherein the diphenylsiloxane content of the elastomer is less than about 2 mole percent.

12. The gastrostomy feeding device according to claim 1, wherein the modified silicone elastomer is endcapped with a material selected from the group consisting of dimethylvinylsiloxane groups, trimethylsiloxy groups, methylphenylvinylsiloxy groups and hydroxyl groups.

13. A gastrostomy feeding device comprising:

an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet, and an internal retaining member for retaining the feeding tube within the stomach, said internal retaining member comprised of a fluoro modified polysiloxane.

14. A gastrostomy feeding device according to claim 13, wherein said fluoro modified polysiloxane comprises a trifluoropropylsiloxane modified dimethylpolysiloxane.

15. A gastrostomy feeding device as defined in claim 13, wherein said polysiloxane comprises a dimethylpolysiloxane.

16. A gastrostomy feeding device as defined in claim 13, wherein the fluoro

modified polysiloxane contains from about 40 mole percent to about 60 mole percent fluoro groups.

17. A gastrostomy feeding device as defined in claim 14, wherein the fluoro modified polysiloxane contains trifluoropropylsiloxane in an amount from about 40 mole percent to about 60 mole percent.

18. A gastrostomy feeding device as defined in claim 13, wherein the fluoro modified polysiloxane is endcapped with a material selected from the group consisting of dimethylvinylsiloxane groups, trimethylsiloxy groups, methylphenylvinylsiloxy groups and hydroxyl groups.

19. A gastrostomy feeding device as defined in claim 13, wherein said fluoro modified polysiloxane contains a filler.

20. A gastrostomy feeding device comprising:

an elongated feeding tube having a first end for insertion through a patient's abdominal wall and a second end including a feeding inlet, and an internal retaining member for retaining the feeding tube within the stomach, said internal retaining member comprised of a phenyl modified polysiloxane, said phenyl modified polysiloxane containing phenyl groups in an amount less than about 25 mole percent.

21. A gastrostomy feeding device as defined in claim 20, wherein the phenyl modified polysiloxane comprises a diphenylsiloxane modified dimethylpolysiloxane.

22. A gastrostomy feeding device as defined in claim 20, wherein said polysiloxane comprises dimethylpolysiloxane.

23. A gastrostomy feeding device as defined in claim 21, wherein said phenyl

modified polysiloxane contains diphenylsiloxane groups in an amount less than about 2 mole percent.

24. A gastrostomy feeding device as defined in claim 20, wherein said phenyl modified polysiloxane contains phenyl groups in an amount less than about 2 mole percent.

25. A gastrostomy feeding device as defined in claim 20, wherein the phenyl modified polysiloxane is endcapped with a material selected from the group consisting of dimethylvinylsiloxane groups, trimethylsiloxy groups, methylphenylvinylsiloxy groups and hydroxyl groups.

26. A gastrostomy feeding device as defined in claim 20, wherein said phenyl modified polysiloxane contains a filler.